IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Stephen James FIELD et al.	)	
Serial No:	10/803,882	)	Art Unit: 3737
Filed:	March 19, 2004	)	Examiner: Roy, Baisakhi
For:	MEDICAL DEVICES	)	Attorney Docket: 0119/0034

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group PLC to whom the inventors assigned the invention per an Assignment recorded on March 19, 2004 at Reel 015122, Frame 0213 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

Co-pending application No. 10/196,151 is believed to be related to the instant case and is on appeal.

TABLE OF AUTHORITIES

STATUS OF CLAIMS

Claim 2 has been cancelled.

Claims 1 and 3-18 stand rejected.

Claims 1 and 3-18 accordingly are pending in this application and are being appealed. The being appealed claims are reproduced in the Claims Appendix.

STATUS OF AMENDMENTS

An amendment after final rejection is filed concurrently with this appeal brief to correct obvious typographical errors in claims 13-18. Claims 13-18 as amended are reproduced in the Claims Appendix.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The instant invention relates to a catheter that is formed of two extruded layers in a first embodiment and three extruded layers in a second embodiment. One of the two extruded layers in the first embodiment is substantially free of gas bubbles while the other of the extruded layers is a bubble-filled material with high ultrasound reflectivity. One of the layers may be thinner than the other. The purpose of a free of bubbles inner layer is to provide a smooth inner passage to the catheter so as to make it as atraumatic as possible for embryos, in the case of a catheter that is used as an embryo transfer catheter. Without this inner layer, the inner surface of the catheter would be interrupted by the occasional bubble which breaks to the surface so that the inner passageway of the catheter would not be as smooth. The purpose of the bubble filled layer is to increase the visibility of the catheter under ultrasonic imaging.

In particular, independent claim 1 relates to a medical device (1) that comprises an elongate portion of plastics material that is extruded with at least a first inner layer (12) of a plastics material and a second layer (13) of a plastics material on an outside of the inner layer. One of the layers is substantially free of gas bubbles, and the other of the layers is co-extruded with the one layer to include gas bubbles dispersed within the material to increase the visibility of the device under ultrasound imaging. The layer substantially free of gas bubbles is thinner than the layer that has the gas bubbles and the layer containing the gas bubbles is covered at a surface by the thinner of the layers. [Figs. 2 and 3; page 4, lines 7-13]

Claim 3 depends from claim 1 and defines the layer that is substantially free of gas bubbles being the inner layer (12). [Fig. 2; page 7, lines 7-13]

Claim 4 depends from claim 1 and defines the second layer (13) being the outer surface of the device. [Fig. 2]

Claim 5 depends from claim 1 and requires that the device further includes a third layer (116) on an outside of the second layer (113). [Figs. 5 and 6; page 6, lines 7-11]

Claims 6 depends from claim 5 and defines the second layer (113) to contain gas bubbles, and the first and third layers (112, 116) being substantially free of gas bubbles. [Figs. 5 and 6; page 6, lines 7-11]

Claim 7 depends from claim 1 and defines the bubbles being in a region extending around the entire circumference of the device. [Page 2, lines 21-22; page 4, lines 15-16]

Claim 8 depends from claim 1 and defines the bubbles to extend in a continuous region along the length of the device. [Page 4, lines 15-16]

Claim 13 depends from claim 1 and defines the device as a catheter having a bore extending along its length. [Page 4, lines 3-6]

Claim 14 depends from claim 13 and defines the inner layer to have an inner surface providing the bore of the catheter. [Page 4, lines 7-9]

Claim 15 depends from claim 13 and defines the plastics material to be transparent to the eye and the density of the bubbles being such as to permit the material within the catheter to be viewed by the eye. [Page 6, line 20 to page 7, line 3]

Independent claim 16 recites a catheter that comprises an elongate shaft (1) of plastics material extruded with an inner layer (12) and an outer layer (13) on the outside of the inner layer. The inner layer is substantially free of gas bubbles, whereas the outer layer coextruded with the inner layer includes gas bubbles dispersed therein to increase the visibility of the catheter under ultrasound imaging. The outer layer is thicker than the inner layer such that the inner surface of the outer layer is covered by the inner layer. [Figs. 2 and 3; page 4, lines 7 to page 5, line 2]

Independent claim 17 recites an embryo transfer catheter that comprises an elongate shaft (1) of transparent plastics material. The shaft is coextruded with an inner layer (12) and an outer layer (13) on the outside of the inner layer. The inner layer is substantially free of gas bubbles such that the inner surface of the outer layer is covered by the inner layer, and the outer layer of the catheter includes gas bubbles dispersed therewithin to increase the visibility of the device under ultrasound imaging. The density

of the bubbles is insufficient to prevent visualization of the embryo in the catheter. The outer layer is thicker than the inner layer. [Figs. 2 and 3; page 6, line 20 to page 7, line 3]

Independent claim 18 recites a catheter that comprises an elongate shaft (1) of plastics material. The shaft is extruded with three layers each of plastics material including an inner layer (112), an outer layer (116), and a middle layer (113) between the inner and the outer layers. The inner and outer layers are substantially free of gas bubbles such that the inner and outer surfaces of the middle layer are covered by the inner and outer layers respectively. The middle layer of the catheter and is extruded to include gas bubbles dispersed therewithin to increase the visibility of the device under ultrasound imaging. The inner and outer layers are thinner than the middle layer. [Figs. 5 and 6; page 6, lines 7-13]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 1 and 3-18 stand rejected under 35 U.S. C. 102(b) as being anticipated by Arterburn (US 4,644,977).

II. Claims 9-12 stand rejected under 35 U.S.C. 103(a) as being obvious over Arterburn.

III. Claim 15 stands rejected under 35 U.S.C. 103(a) as being obvious over Arterburn in view of Glynn (US 5,415,634).

ARGUMENT

As discussed above in the Summary of the Invention section, each of independent claims 1, 16, 17 and 18 requires at minimum an elongate portion of plastics material that is extruded with a first layer and a second layer, with one of the layers being substantially free of gas bubbles and the other layer including gas bubbles dispersed within the material to increase the visibility of the device under ultrasound imaging.

Independent claim 1 specifically requires that the layer substantially free of the gas bubbles be substantially thinner than the layer that has the gas bubbles such that the layer containing the gas bubbles is covered at a surface by the thinner layer.

Independent claim 16 is directed to a catheter and requires that the outer layer of the shaft of the catheter where the gas bubbles are dispersed be thicker than the inner layer which does not have any gas bubbles and that the inner surface of the outer layer be covered by the inner layer.

Independent claim 17 is directed to an embryo transfer catheter that further requires that the density of the bubbles be insufficient to prevent the visualization of an embryo in the catheter.

Independent claim 18 is directed to a catheter that has three layers, with the gas bubbles dispersed in the middle layer sandwiched by the non-gas bubbles inner and outer layers.

All of the claims recite that the dispersed gas bubbles in the gas bubble filled layer increase the visibility of the device/catheter under ultrasound imaging.

I. 35 USC 102(b) Anticipation Rejection of Claims 1 and 3-18 Under Arterburn (US 4,644,977)

"A claim is anticipated only if each and every element as set forth in the claim is found, expressly or inherently described, in a single prior art reference." ... "The identical invention must be shown in as complete detail as is contained in the .... claim. (Cite omitted) The element must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required." MPEP 2131.

Arterburn (US 4,644,977) discloses a reinforced, light-weight flexible hose that is abrasion and stain resistant.[1] Indeed, starting with the first sentence in the "Background of the Invention" section, Arterburn discloses his invention as relating to "flexible hoses consisting of foamed layers protected by a nonfoamed or less-foamed outer cover and an inner tube." Arterburn further discloses that the prior art does teach the co-extrusion of multiple layers of foamed, plastic material to make a flexible lightweight hose, and that the foaming of the material also improves the economics of making such hose because it reduces the density of the hose by using less material per unit length. However, the hoses prior to Arterburn allegedly have a cover that is not resistant to staining or abrasion (Column 1, lines 1-22). To overcome this abrasion and staining problem, Arterburn discloses the application of a thin, non-foamed or substantially less-foamed cover layer over the outermost foamed layer (column 1, lines 32-35). In addition to the application of the thin non-foamed skin layer (16 in the Fig. 1 embodiment), a reinforcement 12, in the form of a netted tube, is placed between the two foamed layers 14 and 20. Thus, the Fig. 1 embodiment of Arterburn has four layers (foam inner layer 20, foamed outer layer 14, non-foamed skin cover 16 and inner liner 18) and the reinforcement tube 12 between foamed layers 18 and 20. Arterburn also discloses the use of a reinforcement layer in each of the other embodiments shown in Figs. 2-5 (24 in Fig. 2, 35 in Fig. 3, 44 in Fig. 4 and 53 in Fig. 5). Thus, Arterburn discloses a hose that has foam layers and a reinforcement tube that renders the hose to be flexible and lightweight.

Independent claim 1 recites a "medical device" that has a layer with gas bubbles dispersed therewithin "to increase the visibility of the device under ultrasound imaging". Independent claim 16 recites a "catheter" with an outer layer that has gas bubbles dispersed therewithin "to increase the visibility of the catheter under ultrasound imaging". Claim 17 recites an "embryo transfer catheter" that has an outer layer that has gas bubbles dispersed therewithin "to increase the visibility of the catheter under ultrasound imaging, when the density of bubbles is insufficient to prevent visualization of an embryo in the catheter". Claim 18 recites a "catheter" that has a middle layer with gas bubbles dispersed therewithin "to increase the visibility of the device under ultrasound imaging".

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[1] Arterburn US 4,644,977 is classified in Class 138 (Pipes and Tubular Conduits) in the patent classification schedule of the USPTO.

In the Office Action, the examiner posits that the "ultrasound visibility" limitation in the claims is directed to "functional language and intended use" and therefore would not be considered. Based on that interpretation, the examiner asserts that the at issue claims read on the structure of the Arterburn hose.

Appellant submits that the examiner has erred at least with respect to her interpretation of the "functional limitation" recited in the claims and also her failure to recognize the subject matter covered by the claim as a whole and particularly the body of each of the claims as defined by its preamble, per discussion below.

MPEP 2173.05(g), entitled "Function Limitation", states:

> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by a specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. (Cite omitted)
>
> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. (Cite omitted)

In contrast to the position taken by the examiner, the USPTO therefore holds unequivocally that there is nothing wrong with the recitation of a functional limitation in association with an element to define a particular capability or purpose served by the element. And this is exactly what each of independent claims 1, 16, 17 and 18 does, for each of those claims recites that a layer of the medical device (or catheter) has gas bubbles dispersed therewithin to increase the visibility of the device (catheter) under ultrasound imaging. Arterburn fails to disclose anything remotely having to do with ultrasound imaging.

Appellants further submit that the examiner has failed to take into account the preamble of the claims in evaluating the claims. In the case at hand, claim 1 recites a medical device, claims 16 and 18 a catheter, and claim 17 an embryo transfer catheter.

The courts have held that the preamble must be taken into consideration if it is necessary to give life, meaning and vitality to a claim. In Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298 (Fed. Cir. 1999), the CAFC states:

> [A] claim preamble has the import that the claim as a whole suggests for it. (Cite omitted) If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or if the claim preamble is "necessary to give life, meaning and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim. (Cites omitted) Indeed, when discussing the "claim" in such a circumstance, there is no meaningful distinction to be drawn between the claim preamble and the rest of the claim, for only together do they comprise the "claim". At 1305.

It is clear that the in issue claims are directed to either a medical device or a catheter (including an embryo transfer catheter) that is subjected to ultrasound imaging. To elaborate, claim 1 does not say "A device". Instead claim 1 recites "A medical device". By doing that, it places claim 1 in the medical field and, presumably under Class 604 (Surgery) or Class 128 (Surgery) of the classification schedule of the US PTO.

In contrast, Arterburn discloses a hose that clearly is not a medical device, a catheter, or an embryo transfer catheter. No person skilled in the art could have construed the hose disclosed by Arterburn to be a medical device or a catheter. Thus, not only does Arterburn not disclose every limitation of each of claims 1 and 16-18, as is required for a section 102 rejection, Arterburn in fact does not have anything to do with the claimed subject matter at issue. Appellants therefore submit that each of independent claims 1, 16, 17 and 18 is not anticipated by Arterburn. Insofar as claims 3-8 and 12-14 each depend, either directly or indirectly, from claim 1, it is further submitted that those dependent claims likewise are not anticipated by Arterburn.

II. Obvious Rejection of Claims 9-11 Under Arterburn

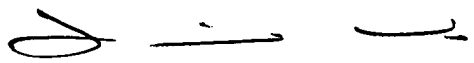
There is no teaching in Arterburn of the respective dimensions of the gas bubbles, as disclosed in claims 9-11, or any suggestion that the dimension of the foams formed in Arterburn be in the micro range as defined in those claims. If anything, the fact that one of the objectives of Arterburn is to economize the material by putting foams throughout the layers of the hose makes it more likely that the dimensions of the foams formed in the layers in the Arterburn hose be of larger dimensions than those recited in claims 9-11.

III. Obvious Rejection of Claim 15 Under the Combination of Arterburn and Glynn (US 5,415,634)

In relying on the combination of Arterburn and Glynn, the examiner states that Glynn is in the same field of endeavor as Arterburn. Appellants submit that this is not the case insofar as Glynn is classified in Class 604 (Surgery), whereas Arterburn is classified in Class 138 (Pipes and Tubular Conduits). Moreover, irrespective of whether or not Glynn discloses a transparent tube, the fact remains that neither Glynn nor Arterburn discloses subjecting a catheter to ultrasound imaging. At best Glynn discloses an inflation tube 60 made from a transparent plastic wounding about a catheter body so that good visibility is provided "within the inflation lumen, i.e., within the inflation tube itself". An inflation tube is not a catheter, particularly when it wounds about the catheter, as taught in Glynn.

For the reasons set forth above, Appellants submit that the claims of the instant application are patentably distinguishable over the cited prior art. Accordingly, the Board is requested to reverse the examiner's rejections.

Respectfully submitted,



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CLAIMS APPENDIX

1. (Previously presented) A medical device comprising an elongate portion of plastics material, the portion being extruded with at least a first, inner layer of a plastics material and a second layer of a plastics material on an outside of the inner layer, wherein one of said layers is substantially free of gas bubbles, wherein the other of said layers of the device is coextruded with the one of the layers to include gas bubbles dispersed within the material of said other layer to increase the visibility of the device under ultrasound imaging, and wherein said layer substantially free of gas bubbles is thinner than said other layer such that the layer containing gas bubbles is covered at a surface by the thinner of the layers.

2. (Canceled)

3. (Original) A device according to Claim 1, wherein said layer substantially free of gas bubbles is said inner layer

4. (Original) A device according to Claim 1, wherein said second layer provides an outer surface of the device.

5. (Original) A device according to Claim 1, including a third layer on an outside of said second layer.

6. (Original) A device according to Claim 5, wherein said second layer contains gas bubbles, and wherein said first and third layers are substantially free of gas bubbles.

7. (Original) A device according to Claim 1, wherein the bubbles are in a region extending around the entire circumference of the device.

8. (Original) A device according to Claim 1, wherein the bubbles extend in a continuous region along the length of the device.

9. (Original) A device according to Claim 1, wherein the gas bubbles have a size in the range 0.1μ to 300μ

10. (Original) A device according to Claim 9, wherein the gas bubbles have a size in the range 1μ to 50μ.

11. (Original) A device according to Claim 10, wherein the gas bubbles have a size in the range 5μ to 10μ.

12. (Original) A device according to Claim 1, wherein the gas bubbles are provided by gas-filled polymer microspheres.

13. (Original) A device according to Claim 1, wherein the device is a catheter having a bore extending along its length.

14. (Original) A device according to Claim 13, wherein said inner layer has an inner surface providing the bore of said catheter.

15. (Original) A device according to Claim 13, wherein said plastics material is transparent to the eye, and wherein the density of bubbles is such as to permit material within the catheter to be viewed by the eye.

16. (Previously presented) A catheter comprising an elongate shaft of plastics material, the shaft being extruded with an inner layer of a plastics material and an outer layer of a plastics material on an outside of the inner layer, wherein said inner layer is substantially free of gas bubbles, wherein said outer layer of the device is coextruded with said inner layer to include gas bubbles dispersed within the plastics material of said outer layer to increase the visibility of the catheter under ultrasound imaging, and wherein said outer layer is thicker than said inner layer such that the inner surface of the outer layer is covered by the inner layer.

17. (Previously presented) An embryo transfer catheter comprising an elongate shaft of transparent plastics material, the shaft being coextruded with an inner layer of a plastics material and an outer layer of a plastics material on an outside of the inner layer, wherein said inner layer is substantially free of gas bubbles such that the inner surface of the outer layer is covered by the inner layer, wherein said outer layer of the catheter includes gas bubbles dispersed within the plastics material of said outer layer to increase the visibility of the catheter under ultrasound imaging, wherein the density of bubbles is insufficient to

prevent visualization of an embryo in the catheter, and wherein said outer layer is thicker than said inner layer.

18. (Previously presented) A catheter comprising an elongate shaft of plastics material, the shaft having three coextruded layers each of a plastics material, wherein the shaft comprises an inner layer, an outer layer and a middle layer between said inner and outer layers, wherein said inner and outer layers are substantially free of gas bubbles such that the inner and outer surfaces of the middle layer are covered by the inner and outer layers respectively, wherein said middle layer of the catheter is extruded to include gas bubbles dispersed within the plastics material of said middle layer to increase the visibility of the catheter under ultrasound imaging, and wherein said inner and outer layers are thinner than said middle layer.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.